DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
2098 Gaither Road
Rockville MD 20850

Roche Diagnostics Corp.
c/o Theresa M. Ambrose, PhD
9115 Hague Rd.
Indianapolis, IN 46250

MAR 2 2005

Re: k050113
Trade/Device Name: Tina-Quant IgG Gen.2
Regulation Number: 21 CFR 866.5510
Regulation Name: Immunoglobulins A, G, M, D, E Immunological Test
Regulatory Class: Class II
Product Code: DEW
Dated: January 14,2005
Received: January 18,2005

Dear Dr. Ambrose:

This letter corrects our substantially equivalent letter of February 8,2005 regarding the Tina-Quant IgG Gen.2 in which the dates for submission and receipt were incorrectly entered as January 4 and January 6,2005 respectively.

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent [(for the indications for use stated in the enclosure)] to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other

requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (sections 531-542 of the Act); 21 CFR 1000-1050.

This letter will allow you to continue marketing your device as described in your Section 510(k) premarket notification. The FDA finding of substantial equivalence of your device to a legally marketed predicate device results in a classification for your device and thus, permits your device to proceed to the market.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please contact the Office of Compliance at (301) 594-3084. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 443-6597 or at its Internet address http://www.fda.gov/cdrh/dsma/dsmamain.html

Sincerely yours,

Robert L. Becker, Jr., M.D., PhD
Director
Division of Immunology and Hematology Devices
Office of In Vitro Diagnostic Device Evaluation and Safety
Center for Devices and Radiological Health

Enclosure

Indications for Use

510(k) Number (if known): K050113

Device Name: Tina-Quant® IgG Gen.2

Indications For Use:

Immunoturbidimetric assay for the quantitative in vitro determination of IgG in human serum, plasma and cerebrospinal fluid (CSF) on Roche automated clinical chemistry analyzers.

Measurement of IgG aids in the diagnosis of abnormal protein metabolism and the body's lack of ability to resist infectious agents.

Prescription Use X AND/OR Over-The-Counter Use

(Part 21 CFR 801 Subpart D) (21 CFR 801 Subpart C)

(PLEASE DO NOT WRITE BELOW THIS LINE-CONTINUE ON ANOTHER PAGE IF NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)

Maria Chan

Division Sign-Off

Office of In Vitro Diagnostic Device Evaluation and Safety

510(k) K050113

FEB - 8 2005

K050113

510(k) Summary

Introduction	According to the requirements of 21 CFR 807.92, the following information provides sufficient detail to understand the basis for a determination of substantial equivalence.
Submitter name, address, contact	Roche Diagnostics 9115 Hague Road Indianapolis, IN 46250 (317) 521-3723 Contact Person: Theresa M. Ambrose
Device Name	Proprietary name: Tina-Quant® IgG Gen.2 Common name: Immunoglobulin G (IgG) Test Classification name: IgG (gamma chain specific) antigen, antiserum, controls
Device Description	The Tina-Quant ® IgG Gen.2 is an immunoturbidimetric assay for the quantitative in vitro determination of IgG in human serum, plasma and cerebrospinal fluid (CSF). Anti-IgG antibodies react with antigen in the sample to form an antigen/antibody complex which is measured turbidimetrically. The assay contains a standard application for measurement of IgG in human serum and plasma and a sensitive application for measurement of IgG in CSF.
Intended use	Immunoturbidimetric assay for the quantitative in vitro determination of IgG in human serum, plasma and cerebrospinal fluid (CSF) on Roche automated clinical chemistry analyzers. Note: Serum and plasma cleared under K040434.
Indications for Use	Measurement of IgG aids in the diagnosis of abnormal protein metabolism and the body's lack of ability to resist infectious agents.

510(k) Summary, Continued

Substantial equivalence

The Tina-Quanta IgG Gen.2 test system is substantially equivalent to other devices legally marketed in the United States. We claim equivalence to in Dade Behring N Antisera to Human Immunoglobulins (IgG, IgA, and IgM) IgG assay on the BN I1 cleared under K943997. Both products are intended for use in the quantitative determination of IgG in human CSF.

Substantial equivalence - comparison

The following table compares the Tina-Quanta IgG Gen.2 test system with the predicate device.

Feature	Tina-Quant ® IgG Gen.2	Dade-Behring N Antisera to Human Immunoglobulins IgG *on* BN II (predicate)
Intended Use	Immunoturbidimetric assay for the quantitative in vitro determination of IgG in human serum, plasma and cerebrospinal fluid (CSF) on Roche automated clinical analyzers.	In vitro diagnostic reagents for the quantitative determination of immunoglobulims (IgG, IgA, and IgM) in human serum as well as of IgG in human urine and cerebrospinal fluid (CSF) using the BN systems.
Indication for Use	Measurement of IgG aids in the diagnosis of abnormal protein metabolism and the body's lack of ability to resist infectious agents.	Quantitative determination of the immunoglobulins can provide important information on the humoral immune status.
Assay Protocol	Immunoturbidimetric assay	Immunochemical reaction with formation of immune complexes and measurement of scattered light intensity (nephelometric).
Traceability / Standardization	CRM 470	CRM 470

Sample Types	Serum, plasma, CSF	Serum, plasma, urine, CSF
Reagent Stability	Unopened at 2-8°C: up to the expiration date Opened and refrigerated on the analyzer: 90 days	Shelf life at 2-8°C : until expiration date Opened, capped at 2-8°C: 4 weeks On-board: 5 days at 8 hours each or comparable period of time (maximum 40 hours)
Controls	Sensitive application (CSF): Precinorm PUC (Proteins in Urine/CSF) / Precipath PUC Standard application (serum, plasma) :Precinorm Protein / Precipath Protein	For IgG in urine or CSF: N/T Protein Control LC (human)
Calibrator	Sensitive application (CSF): C.f.a.s. (Calibrator for automated systems) PUC Standard application (serum, plasma) : C.f.a.s. Proteins	N Proteins Standard SL (human)
Instrument	Roche/Hitachi family of analyzers	BN Systems
Limitations	Carryover: to avoid carryover a sample probe wash is recommended. Icterus: no significant interference up to an I index of 60 (60 mg/dL conjugated or unconjugated bilirubin). Falsely low results due to antigen excess may occur above 1400 mg/L	Turbidity and particles in the sample may interfere with determination Samples containing particles must be centrifuged prior to testing.
Ferformance Characteristics for CSF application		
Measuring Range	2 0 – 200 mg/L 2-1000 mg/L with rerun (upper limits depend on highest standard concentration)	Depends on concentration of proteins in N Protein Standard SL

Expected Values for IgG in CSF	10-30 mg/L (according to CRM 470 standardization)	Below 34 mg/L (with reference to CRM 470 _

Precision	Within-run CV 0.65% @ 167.8 mg/L control sera 1.38% @ 320.7 mg/L control sera 5.74% @ 11.7 mg/L human CSF Between-run CV 1.27% @ 166.6 mg/L control sera 2.07% @ 327.7 mg/L control sera 6.52% @ 13.21 mg/L human CSF	Intra-Assay CV 2.1 % @ 13.5 g/L Inter-Assay CV 2.7 % @ 13.2 g/L Note: no separate values are given for CSF precision
Analytical Sensitivity	2 mg/L	Established by lower limit of reference curve; depends on concentration of proteins in N Protein Standard SL
Method Comparison	Tina-Quant ® IgG Gen.2 (x) vs. Dade-Behring IgG on BNII (y) 54 samples (6.17-65.5 mg/L) Slope = 1.042 Intercept= 1-3.903 r= 0.988	N/A